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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,949	07/31/2003	Masahiro Ishima	03461C/HG	5027

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,949	ISHIMA ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3, 5, 7, 10, 13, 16, 24-41* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *3,5,10,13,16 and 24-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed October 27, 2006 in response to the Office Action of August 2, 2006 is acknowledged and has been entered. Claims 1, 2, 4, 6, 8, 9, 11, 12, 14, 15, and 17-23 have been canceled. New claims 24-41 have been added. Previously withdrawn claims 5 and 10 are examined on the merits. Thus claims 3, 5, 10, 13, 16, and 24-41 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

Applicants submit that the peptide structure of formula (II) of claim 5, the peptide structure of formula (III) of claim 7 and the peptide structure of formula (VI) of claim 10 are also analogous to the peptide structure of formula (I). Therefore examination of the peptides of formula II, III, and VI would not create an excessive burden on the Examiner.

Examiner agrees to search formulas II and VI, in addition to formulas I, IV, and V. Formula III will not be examined because this formula is representing a cyclic peptide unlike the other formulas. Searching formula III would require a separate search in commercial databases, which would be burdensome on the Office.

Claim Rejections - 35 USC § 112

Rejection of Claims 1, 2, and 4 under 35 U.S.C. 112, second paragraph, **is moot** because Applicant canceled the claims.

Rejection of claims 1, 2, 4, 6, 8, 11, 12, 14, and 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is moot** because Applicant canceled the claims.

Rejection of claim 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** because the claim defined the structure of the claimed derivative.

Rejection of claims 1, 2, 4, 6, 8, 11, 12, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the structure (I), (IV), and (V), does not reasonably provide enablement for all structures that encompass the amino acids and the functional groups recited in the claims **is moot** because Applicant canceled the claims.

Rejection of claim 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** because the claim defined the structure of the claimed derivative.

Claim Rejections - 35 USC § 101

Rejection of claims 3, 13, and 16 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter **is withdrawn** in view of Applicants amendments to the claims.

Claim Rejections - 35 USC § 112

Claims 3, 13, 16, 24, 25, 28, 29, 32, 33 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that *Pseudomonas* sp. RtIB026 deposited under accession number FERM BP-7436 is required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of *Pseudomonas* sp. RtIB026 deposited under accession number FERM BP-7436. See 37 CFR 1.802. One cannot practice the claimed invention without the *Pseudomonas* sp. RtIB026 deposited under accession number FERM BP-7436. One cannot obtain the claimed cyclic peptides without access to *Pseudomonas* sp. RtIB026 deposited under accession number FERM BP-7436. Therefore, access to *Pseudomonas* sp. RtIB026 deposited under accession number FERM BP-7436is required to practice the invention. The specification does not provide a repeatable method for *Pseudomonas* sp. RtIB026 deposited under accession number FERM BP-7436 without access to the *Pseudomonas* sp. RtIB026 deposited under accession number FERM BP-7436 and it does not appear to be readily available material.

Deposit of *Pseudomonas* sp. RtIB026 deposited under accession number FERM BP-7436 in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claims 3, 5, 10, 13, 16, and 24-41 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of a number of fish species and domestic animals using the currently claimed compositions, does not reasonably provide enablement for treatment of any organism or subject such as for example mouse or human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The claims are broadly drawn to an antiviral composition, a method of preventing virus infection and a method of treating a subject suffering from infection with a virus, by administering the compositions comprising peptides defined in formulas I, II, IV, V, and VI. The specification does not provide sufficient support to enable one skilled in the art to practice the invention as claimed. The recitation of "antiviral composition" is interpreted, such that the composition must have an antiviral effect against any virus. Applicants provided working

examples showing that the claimed composition has an antiviral effect against hematopoietic necrosis virus (IHNV), which infects salmon species, rhabdovirus (EVA), which infects American eels and rhabdovirus (EVEX), which infects European eels, as well as herpes and influenza viruses infecting domestic animals. Based on Applicant's examples one of ordinary skill in the art would not be able to directly extrapolate, that the claimed composition may have an antiviral effect against other viruses. The art teaches that cyclic peptides are effective agents against viruses such as herpes simplex virus (see US Patent 5,258,493). However taken the complex structure of various cyclic peptides one cannot reasonably extrapolate that when the particular peptide composition is effective against one virus, the same composition should also be effective against other viruses. For the above reasons one of skill in the art would be unable to use the claimed composition for treatment or prevention of viral infections other that the infections caused by the viruses that have been shown to be sensitive to the currently claimed compositions.

Thus considering the breadth of the current claims, which read on treating and preventing infections caused by any viruses, one of ordinary skill in the art would require an undue amount of experimentation in order to practice the claimed invention in its full scope.

Conclusion

Structures I, II, IV, V, and VI are free of prior art of record.

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB
Agnieszka Boesen, Ph.D.
1/16/2007

Stacy B. Chen 1/16/07
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